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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,019	02/27/2004	Jochen Goerlitzer	DEAV2003/0017 US NP	8090

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EXAMINER	
PAVIGLIANITI, ANTHONY JOSEPH	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,019	GOERLITZER ET AL.	
	Examiner	Art Unit	
	Anthony J. Paviglianiti	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 19 are pending in the application and were subject to the following restriction. **Claims 13 - 19** were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a non-elected invention; accordingly, examination was conducted on **Claims 1 – 12**.

Priority

This application claims benefit of U.S. Provisional Application No. 60/494,911, with filing date August 13, 2003.

Acknowledgement is made of applicant's claim for foreign priority under 35 U.S.C. §§119(a) - (d), by German Patent Application No. DE 10308353.7, with filing date February 27, 2003.

Applicant cannot rely upon the foreign priority papers to overcome the following rejections based on 35 U.S.C. §102(a), because an English translation of DE 10308353.7 has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Information Disclosure Statement

There was no Information Disclosure Statement filed with this application as of the date of this office action.

Specification

The Specification is objected to because it does not state the claim to benefit of the U.S. Provisional Application No. 60/494,911, with filing date August 13, 2003. See 37 C.F.R. §1.78.

If applicant desires benefit of a previously filed application under 35 U.S.C. 111(b), specific reference to the earlier filed application must be made in the instant application. For

benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition

must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Election/Restrictions

The Markush groups set forth in the claims include both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. **For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121,** wherein an Invention is a set of patentably distinct inventions of a broad statutory category (e.g., compounds, methods of use, methods of making, etc.):

I. **Claims 1 – 12**, drawn to products of formula (I), classified in class 548, subclass 236, and other classes and subclasses.

II. **Claims 13 – 19,** drawn methods of use of products of formula (I), classified in class 514, subclass 374, and other subclasses.

In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. §121 as follows:

In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984), restriction of a Markush group is proper where the compounds with the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).

If **Group I or Group II** is elected, **an election of a single compound is further required**, including an exact definition of each substitution on the base molecule, where a single member at each substituent group is selected. If the base molecule has variable groups **Ring A, Ring B**, $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$, $\mathbf{R^4}$, $\mathbf{R^5}$, **X**, and **Y**, and, for example, **Ring B** is recited to represent:

> "a) phenyl; or
> b) (C_3-C_8)-cycloalkyl, an 8-, 9-, 10, 11-, 12, 13- or 14-membered aromatic ring, or a 5-, 6- 7-, 8-, 9-, 10-, 11- or 12-membered heteroaromatic ring optionally containing one, two, three or four heteroatoms selected from the group consisting of N, O, or S;"

then Applicant must select a single value for **Ring A**, such as phenyl, and so on for **Ring A**, $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$, $\mathbf{R^4}$, $\mathbf{R^5}$, **X**, and **Y**, such that there are specific values representing each variable and a single compound is identified. One suggestion for the election of a single compound is to select one of Examples 1 – 13 in the Specification on pp. 43 - 50.

Upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar as to be within the same inventive concept and reduction to

practice). The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses.

Examination will then proceed on the elected compound *and* the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits.

Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making the compounds under investigation. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

All compounds falling outside of the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. §121 and 37 C.F.R. §1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. §121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP §608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP §806.04, MPEP §808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group); i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in

accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other, because of the following reasons:

Group I and **Group II** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially-different process of using that product. See MPEP §806.05(h). Applying this rule to the instant case, one of the methods of use claimed for these products, treatment of dyslipidemia (**Claim 16**), may be practiced with another materially different product, such as the pharmaceutical product atorvastatin. See, e.g., Stein, E., "Managing Dyslipidemia in the High-Risk Patient," Am. J. Card., vol. 89(suppl.), pages 50C-57C (2002) at page 51C, col. 1, lines 15 – 16.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper, and not to restrict would impose a serious burden in the examination of this application.

Advisory of Rejoinder

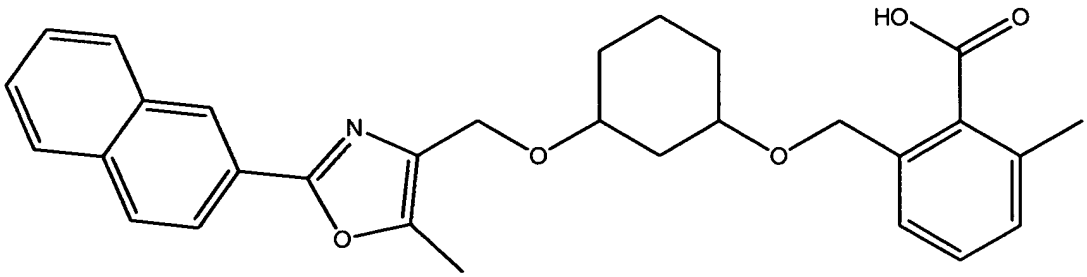
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election by Applicant:

During a telephone conversation with Barbara Kurys, Esq., on April 1, 2005, the above restriction requirements were discussed, and an election was made, without traverse, of **Group I,** and an election of the **compound 2-Methyl-6-[(1R,3S)3-(5-methyl-2-naphthalen-2-yloxazol-4-ylmethoxy) cyclohexyloxymethyl] benzoic acid**, which has the chemical structure:



. In making the election, Ms. Kurys expressly reserved the right to rejoin "method of use" claims for examination for patentability if a product claim is found to be allowable.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed. 37 C.F.R. §1.143. Applicant is further advised that a reply to this requirement must include an identification of the specific compound that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

In accordance with MPEP §821.04 and In re Ochiai, *supra*, process claims which are commensurate in scope with the allowed product claims will be rejoined (following a finding that one or more product claims are allowable) and examined for patentability, including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

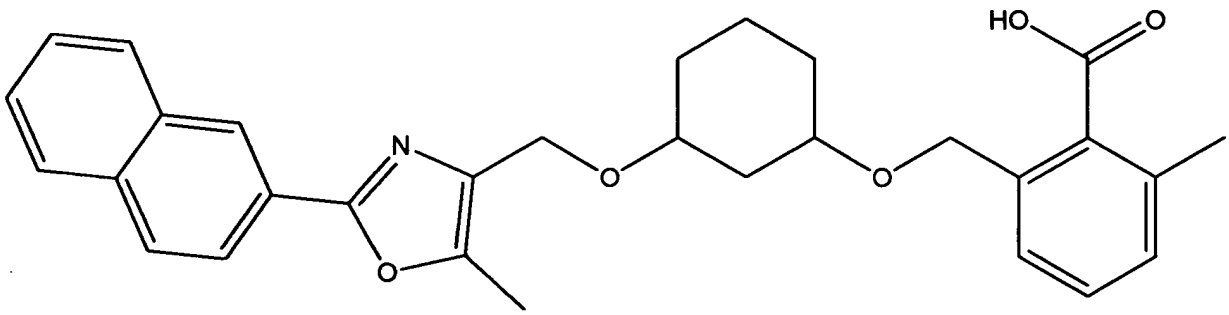
Claims 13 - 19 were withdrawn from further consideration pursuant to 37 C.F.R. §1.142(b) as being drawn to a non-elected invention.

Analysis of Claims 1 – 12 (Prior Art Searched)

The invention was searched as follows:

1) Elected Compound

The elected compound, 2-Methyl-6-[(1R,3S)3-(5-methyl-2-naphthalen-2-yloxazol-4-ylmethoxy) cyclohexyloxymethyl] benzoic acid, which has the chemical structure:

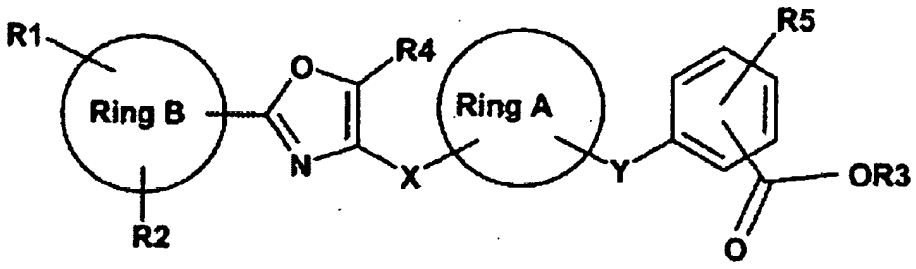


was searched and appears to be free of the prior art. The search was then expanded as described below.

2) Expansion of search to compounds within same patent classification as elected invention

The search of the prior art was expanded to include related compounds in the same general patent classification(s) as the elected compound:

Specifically, the search was expanded several times to include the following compounds of formula (I):



, wherein:

Ring A is *any* $C_3 - C_8$ carbocyclic group, in which bonds could be saturated or unsaturated [but *not* aromatic] and where any of the carbocyclic carbons may be substituted by oxygen atoms;

Ring B is phenyl; or a $C_3 - C_8$ carbocyclic group; or an 8 – 14 membered aromatic ring; or a 5 – 12-membered heterocyclic ring with 1 – 4 heteroatoms (N, O, or S);

R^1 [*where **Ring B** is phenyl*] is SCF_3, OCF_2-CHF_2, O-phenyl or O-(C_1-C_6)-alkyl-O-(C_1-C_3)-alkyl; or

[*where **Ring B** is a $C_3 - C_8$ carbocyclic group; or an 8 – 14-membered aromatic ring; or a 5 – 12-membered heterocyclic ring*] is H, F, Cl, Br, OH, NO_2, CF_3, OCF_3, OCF_2-CF_3, –SCF_3, OCF_2-CHF_2, O-phenyl, (C_1-C_6)alkyl, O-(C_1-C_6)alkyl, or O-(C_1-C_6)-alkyl-O-(C_1-C_3)-alkyl; or

[*where **Ring B** is phenyl and **R^4** is phenyl*] is (C_1-C_6)alkyl, or O-(C_1-C_6)alkyl;

R^2 is H or CF_3;

R^3 is H or (C_1-C_6)alkyl;

R^4 [*where **Ring B** is phenyl*] is phenyl; or

[*where **Ring B** is a $C_3 - C_8$ carbocyclic group; or an 8 – 14-membered aromatic ring; or a 5 – 12-membered heterocyclic ring*] is H, F, Cl, Br, OH, NO_2, CF_3, OCF_3, $(C_1\text{-}C_6)$alkyl, O-$(C_1\text{-}C_6)$alkyl; or

[*where **Ring B** is phenyl and R^1 is SCF_3, $OCF_2\text{-}CHF_2$, O-phenyl or O-$(C_1\text{-}C_6)$-alkyl-O-$(C_1\text{-}C_3)$-alkyl*] is $(C_1\text{-}C_6)$alkyl;

R^5 is H, F, Cl, Br, OH, NO_2, CF_3, OCF_3, $(C_1\text{-}C_6)$alkyl, O-$(C_1\text{-}C_6)$alkyl;

X is $(C_1\text{-}C_6)$ alkanediyl, where one or more of the carbon atoms were optionally substituted by oxygen atoms;

Y is $(C_1\text{-}C_6)$ alkanediyl, where one or more of the carbon atoms were optionally substituted by oxygen atoms;

During the "expanded" search, the following prior art was found and serves as the basis for the rejections below.

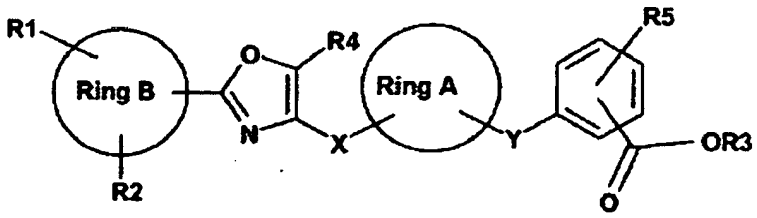
Claim Rejections - 35 USC § 102(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102(a) that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

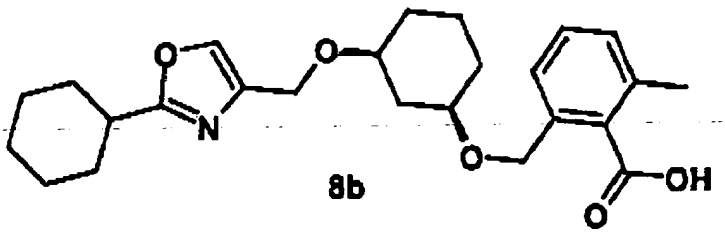
Claims 1 - 12 are rejected under 35 U.S.C. §102(a) as being anticipated by German Patent Application DE 101 42 734 A1, published March 27, 2003, to inventors H. Glombik, et al.

Specifically, the present invention claims chemical compounds of formula (I),



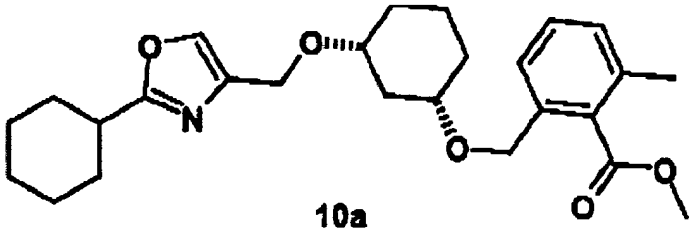
. The prior art discloses compounds

with the following chemical structures:



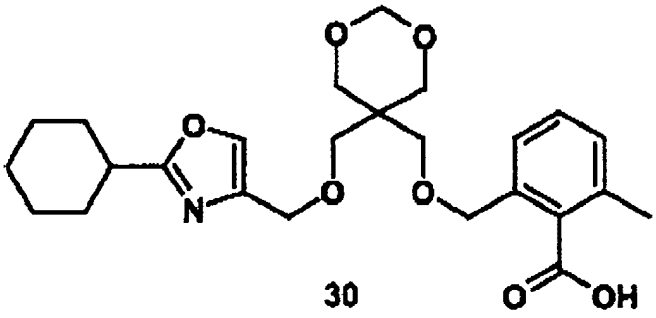
8b

(Compound 8b, p. 11, lines 25 – 35);



10a

(Compound 10a, p. 11, lines 54 – 62);



30

and (Compound 30, p. 18, lines 21 – 39).

Where the variables in formula (I) of the present invention are: (1) **Ring A** is cyclohexane; (2) **Ring B** is cyclohexane; (3) $\mathbf{R^1 - R^5}$ are each hydrogen; (4) **X** is CH_2-O; and (5) **Y** is CH_2-O; then the compounds of the present invention in **Claims 1, 2, 3, 4, 5, 6** and **7** are directly anticipated by "Compound 8b" and "Compound 10a" from the prior art, as drawn above.

Where the variables in formula (I) of the present invention are: (1) **Ring A** is 1,3-dioxane; (2) **Ring B** is cyclohexane; (3) $\mathbf{R^1 - R^5}$ are each hydrogen; (4) **X** is CH_2-O-CH_2; and (5) **Y** is CH_2-O-CH_2; then the compounds of the present invention in **Claims 1, 4 and 5** are directly

anticipated by "Compound 30" from the prior art, as drawn above. [**Claims 2, 3, 6 and** 7 limit **X** and/or **Y** to CH_2-O and are not anticipated by "Compound 30"].

Claim 8 (pharmaceutical composition of claim 1 and a carrier) is anticipated by German Patent Application DE 101 42 734 at page 3, lines 30 – 57 and p. 24, lines 8 – 11.

Claim 9 (pharmaceutical composition of claim 6 and at least one other active ingredient) is anticipated by German Patent Application DE 101 42 734 at p. 24, lines 9 – 10.

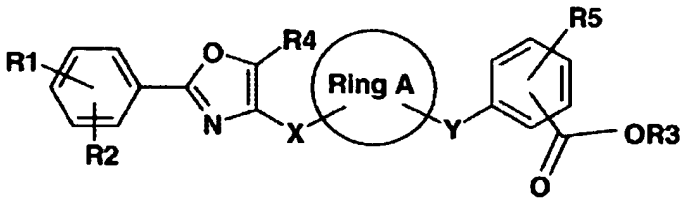
Claim 10 (pharmaceutical composition where additional ingredient has favorable effects on metabolic disturbances) is anticipated by German Patent Application DE 101 42 734 at p. 7, lines 28 et seq.

Claim 11 (pharmaceutical composition where additional ingredient is antidiabetic) is anticipated by German Patent Application DE 101 42 734 at p. 6, lines 18 – 22.

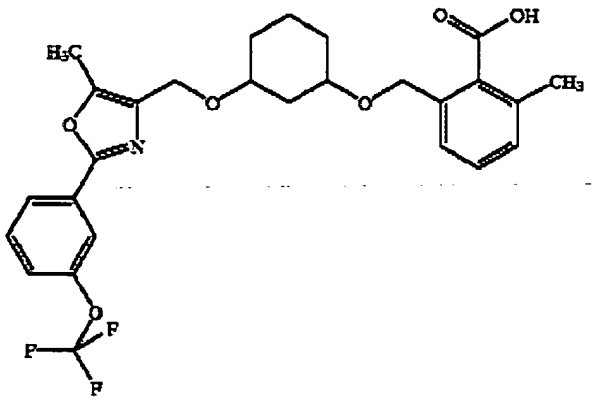
Claim 12 (pharmaceutical composition where additional ingredient is lipid modulator) is anticipated by German Patent Application DE 101 42 734 at p. 6, lines 36 - 42.

The foregoing rejection may be overcome by providing an English language translation of the priority document German Patent Application No. DE 10308353.7, demonstrating that the present invention pre-dated the publication of German Patent Application DE 101 42 734.

The closest prior art, other than the reference cited above, was found in **U.S. Patent 6,624,185** (published as US 2003/0144332 A1 on July 31, 2003), which disclosed compounds of genus chemical structure:

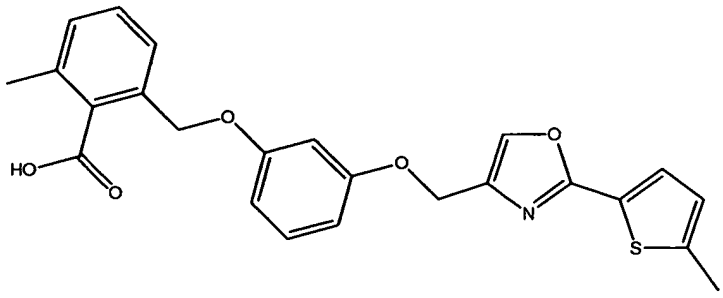


, including a

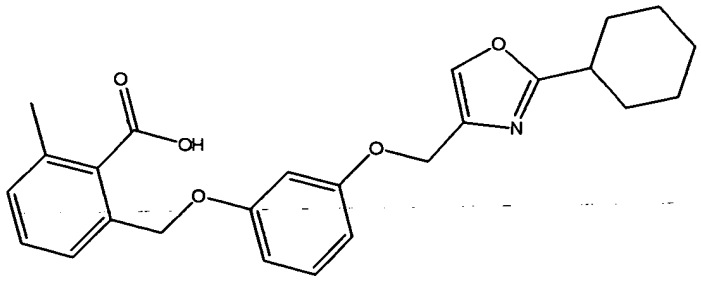


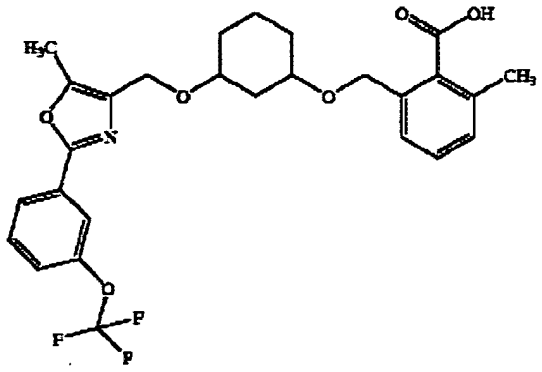
compound of chemical structure (Example XLII, col. 45, lines 34 – 67). As in the present invention, these compounds in the prior art were claimed as useful for treatment of dyslipidemia, etc. However, **U.S. Patent 6,624,185** does not anticipate or render obvious the compounds of the present invention because the present invention limits the values of $\mathbf{R^1}$ to SCF_3, OCF_2-CHF_2, O-phenyl or O-(C_1-C_6)-alkyl-O-(C_1-C_3)-alkyl whenever "Ring B" is defined as a phenyl group (as in **U.S. Patent 6,624,185**), but the prior art limits $\mathbf{R^1}$ to H, F, Cl, Br, OH, NO_2, CF_3, OCF_3 [see Example XLII], (C_1-C_6)-alkyl or O-(C_1-C_6)-alkyl.

Another prior art reference disclosing similar compounds used for treatment of hyperlipidemia is **WO 00/64876** (published November 2, 2000), which disclosed compounds of



structure: (Example 7w, page 107, lines 17 – 23);

and  (Example 7x, page 107, lines 25 – 31), which do not anticipate or render obvious the compounds of the present invention because, in the prior art, "**Ring A**" is an *aromatic* group (i.e., a phenylene group); but, in the present invention, "**Ring A**" is limited to "(C_3-C_8)-cycloalkenediyl" i.e., a *non-aromatic* group.

Another prior art reference disclosing similar compounds is **WO 03/020269** (published March 13, 2003), which discloses  (Compound 64 at p. 66, lines 9 – 14). Although this compound is close art to the present invention, it did not anticipate or render obvious the claims of the present invention, because the present invention limits the values of $\mathbf{R^1}$ to SCF_3, OCF_2-CHF_2, O-phenyl or O-(C_1-C_6)-alkyl-O-(C_1-C_3)-alkyl whenever "**Ring B**" is a phenyl ring (as in **WO 03/020269**). Since the close prior art has $\mathbf{R^1}$ as OCF_3 (not among the values in the present invention), there is no issue of obviousness-type double patenting, even though the assignee (Aventis Pharma Deutschland GmbH) and several inventors (Heiner Glombik, Eugen Falk, Stefanie Keil, Hans-Ludwig Schaefer and Wolfgang Wendler) are shared in common with the present application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

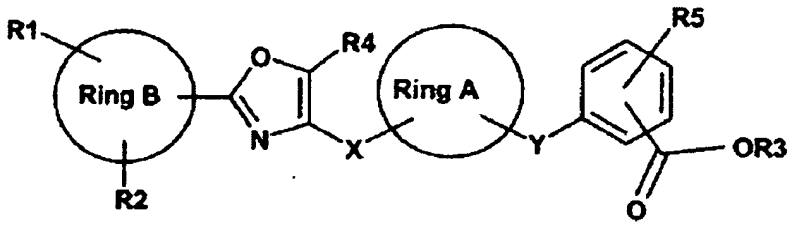
Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and **12** of the instant application are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **Co-pending U.S. Application No. 10/789,281** (published as US 2004/0209932). Although the conflicting claims are not identical, they are not patentably distinct from each other because **Claims 1 – 12** of the present invention and Claims 1, 3, 5, 19, 20, 21, 22 and 23 of the co-pending application claim many of the same compounds and related compositions. In addition,

the compounds of both inventions are claimed to have the same biological activity and uses; i.e., as modulators of lipid or carbohydrate metabolism. See Specification at page 1, lines 15 – 16.

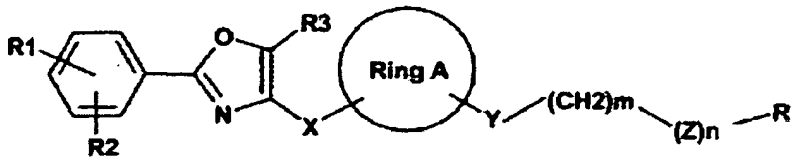
The present application and co-pending application share all eight inventors in common and have a common assignee, Aventis Pharma Deutschland GmbH.

DETERMINING THE SCOPE AND CONTENTS OF THE CO-PENDING APPLICATIONS

Specifically, the present invention claims chemical compounds of formula (I),



. The co-pending application, U.S. Application No. 10/789,281, claims chemical compounds of formula (I),



. The range of values for variables **Ring A, Ring B**, $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$, $\mathbf{R^4}$, $\mathbf{R^5}$, **X**, **Y**, **R**, **m** and **n** are such that both inventions encompass many of the same chemical compounds; for example, when **Ring A** is cyclohexane, attached at the 1,3 positions in a *cis* configuration; **Ring B** [in the present application] is a phenyl group; $\mathbf{R^1}$ is a SCF_3 group; $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are each a hydrogen atom; $\mathbf{R^5}$ is -OH, **X** is CH_2-O; and [in the co-pending application] **Y** is oxygen, **m** is 1, **n** is 0 and **R** is a phenyl group substituted by -COOH and $-CH_3$.

Both the present application and co-pending application claim the pharmaceutical composition of the compound and a carrier (**Claim 8** and Claim 19, respectively); the pharmaceutical composition plus an additional active ingredient (**Claim 9** and Claim 20); the pharmaceutical composition plus an additional active ingredient acting on metabolic disturbances (**Claim 10** and Claim 21); the pharmaceutical composition plus an additional active ingredient that is an antidiabetic (**Claim 11** and 22); and the pharmaceutical composition plus an additional active ingredient that is a lipid modulator (**Claim 12** and Claim 23).

ASCERTAINING THE DIFFERENCES BETWEEN THE CO-PENDING APPLICATION AND THE CLAIMS AT ISSUE

The present application and the co-pending application are different in that the overall scope of the claimed compounds differ from one another; i.e., while the compounds claimed show considerable overlap, there are compounds found in each application which would not be claimed by the other. For example, the present application's **Ring B** may be a phenyl ring (as in the co-pending application) but also may be a saturated carbocyclic ring or heterocyclic ring. Conversely, in the co-pending application, $\mathbf{R^1}$ may be H, F, Cl, Br, SF_5, S-$(C_1$-$C_6)$-alkyl, CF_3, OCF_3, $(C_1$-$C_6)$-alkyl, O-$(C_1$-$C_6)$-alkyl, SCF_3, phenoxy, OCF_2CHF_2, etc., while the present invention limits $\mathbf{R^1}$ to SCF_3, OCF_2-CHF_2, O-phenyl or O-$(C_1$-$C_6)$-alkyl-O-$(C_1$-$C_3)$-alkyl when **Ring B** is a phenyl group.

In addition, the two applications differ in their use of variables to describe the invention; the linking chain between **Ring A** and the phenyl ring is simply "**Y**" in the present invention but is "$\mathbf{Y} - (CH_2)_m - (\mathbf{Z})_n$" in the co-pending application, although the values assigned to these variables permit considerable overlap in the linking chain.

There are no differences between the "pharmaceutical composition" claims in the present application (**Claims 8 – 12**) and the co-pending application (Claims 19 – 23).

RESOLVING THE LEVEL OF ORDINARY SKILL IN THE PERTINENT ART

It would have been obvious to one of ordinary skill in the art to at the time of this application to select values for variables **Ring A, Ring B, R^1, R^2, R^3, R^4, R^5, X, Y, R, m** and **n** in the two inventions in such a way that there was overlap among the compounds claimed in the present application and co-pending application, particularly in view of the fact that both inventions were intended for the same use: i.e., modulating lipid or glucose metabolism. Compounds of similar structure to the present invention were already described in the art for treatment of hyperlipidemia and diabetes. See Specification at page 1, lines 11 – 14. The skilled artisan would have been motivated to synthesize compounds from either application which were structurally similar to those compounds already disclosed in the art as effective for these particular intended uses in order to improve the likelihood of success.

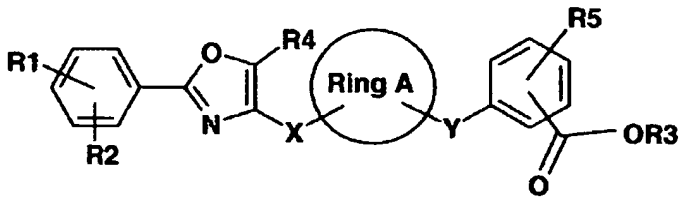
The claims for "pharmaceutical compositions" (with a carrier and/or another active ingredient active) are identical between the two applications; however, **Claims 8 – 12** are rejected as "obviousness-type double patenting" rather than as statutory double patenting because the underlying compounds used in the pharmaceutical compositions were not claimed in both applications in exactly the same manner, as described above.

Therefore, absent a showing of unobvious and superior properties, the compounds and compositions in **Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11** and **12** of the instant application would have been obvious to one skilled in the art based on the disclosure in the co-pending application 10/789,281, and Claims 1 – 12 are therefore rejected as obviousness-type double patenting.

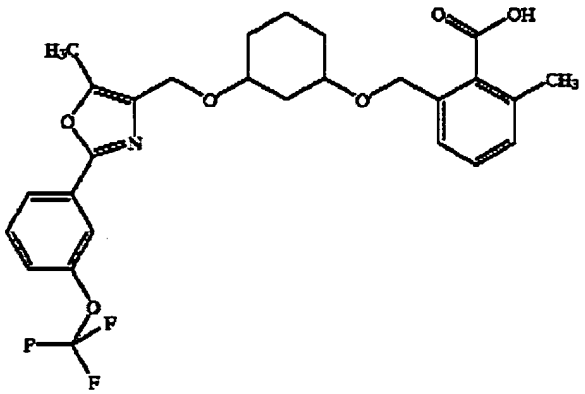
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Similar claims patented or claimed by the same inventors which are not double patenting

U.S. Patent 6,624,185 (published as US 2003/0144332 A1 on July 31, 2003), which disclosed compounds of genus chemical structure:



, including a compound of chemical structure

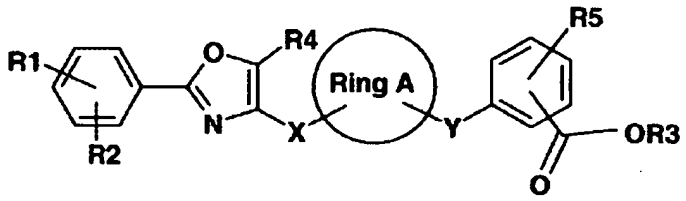


(Example XLII, col. 45, lines 34 – 67).

As in the present invention, these compounds in the prior art were claimed as useful for treatment of dyslipidemia, etc. However, **U.S. Patent 6,624,185** does not anticipate or render obvious the compounds of the present invention because the present invention limits the values of $\mathbf{R^1}$ to SCF_3, OCF_2-CHF_2, O-phenyl or O-(C_1-C_6)-alkyl-O-(C_1-C_3)-alkyl whenever "**Ring B**" is defined as a phenyl group (as in **U.S. Patent 6,624,185**), but the prior art limits $\mathbf{R^1}$ to H, F, Cl, Br, OH, NO_2, CF_3, OCF_3 [see Example XLII], (C_1-C_6)-alkyl or O-(C_1-C_6)-alkyl; therefore, there

is no obviousness-type double patenting issue with **U.S. Patent 6,624,185**, even though the assignee and several inventors are shared in common.

Co-pending U.S. application No. 10/631,867, for which a Notice of Allowability was sent November 24, 2004 (but no patent has yet issued), claims chemical compounds of the following structure, which are similar to those in the present application:



. However, once again, the present application limits the values of $\mathbf{R^1}$ to SCF_3, OCF_2-CHF_2, O-phenyl or O-(C_1-C_6)-alkyl-O-(C_1-C_3)-alkyl whenever "**Ring B**" is a phenyl ring (as in this co-pending application), while the co-pending application limits $\mathbf{R^1}$ to H, F, Cl, Br, CF_3, OCF_3, CN, CH_3 or OCH_3, none of which anticipate or render obvious the present invention; therefore, there is no issue of obviousness-type double patenting, even though the assignee and several inventors are shared in common.

Co-pending U.S. application No. 10/789,865 also claims compounds which are similar to those in the present invention but differs in that "**Ring B**" in the prior art is not benzoic acid or an alkyl ester of benzoic acid, as required in the present invention, and, as before, there is no issue of obviousness-type double patenting.

Claim Objections

On page 53, line 9, **Claim 2** has "R" instead of "R2"; appropriate correction is required.

Although **Claims 13 – 19** were withdrawn from consideration at this time, "resistance" is misspelled (page 57, line 8), and "sequelae" is misspelled (page 57, line 16).

Conclusion

Claims 1 - 12 are rejected under 35 U.S.C. §102(a).

Claims 1 – 12 are also rejected as (provisional) obviousness-type double patenting.

Claim 2 is objected to for a typographical error.

The **Specification** is objected to for failing to state the claimed U.S. priority document.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

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